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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,147	08/30/2006	Ryoichi Imanaka	TAM-066	6163

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EXAMINER	
LUNDGREN, JEFFREY S	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,147	IMANAKA ET AL.	
	Examiner	Art Unit	
	JEFFREY S. LUNDGREN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 28-30 are pending in the instant application and are the subject of the Office Action below.

Previous Rejections are Withdrawn

The previous grounds of rejection have been withdrawn in part to Applicants' amendments to the claims, and the arguments provided in the response.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is generally ambiguous and the metes and bounds cannot reasonably be determined. For example, the phrase "controlling a de-protective reaction of the protective group of a nucleotide *by giving a wavelength dependency to the light wavelength absorption characteristics of the protective group*" is not at all clear. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 28 and 30 rejected under 35 U.S.C. § 103(a) as being unpatentable over Cattell, U.S. Patent No. 6,180,351, issued on January 30, 2001, in view of Pirrung et al., U.S. Patent No. 5,405,783, issued on April 11, 1995.

Claim 28 is directed to a method of removing a protective group of a nucleotide which comprises: forming storing regions and addresses identifying the storing regions on a track which can be tracked by an optical beam on a substrate;

arranging in two or more of each of said storing regions a nucleotide having a protective group;

selecting a storing region in which a nucleotide having protective group is arranged by reading the address identifying said storing region by said optical beam;

irradiating the nucleotide having a protective group and arranged in the selected storing region by said optical beam; and

removing the protective group o£ the nucleotide having the protective group,

wherein each of said storing regions has: 1) a form o£ a concave region or a convex region of a first pregroove on said substrate; **or** 2) a flat region on said substrate. Note the "track" is interpreted to be a row or column on the array, or a line or route along which something travels or moves, such as an optical scanner.

Cattell is directed towards a method of generating an addressable array of biopolymers, such as DNA probes, on a substrate. The method includes receiving from a remote station, information on a layout of the array and an associated first identifier. A local identifier is generated corresponding to the first identifier and associated array, the local identifier being shorter in length than the corresponding first identifier. The addressable array is fabricated on the substrate in accordance with the received layout information. A first copy of the local

identifier is applied to the substrate or a housing carrying the substrate. Cattell specifically teaches:

> "The above described components in FIG. 4 represent an apparatus for producing ***an addressable array***, which is sometimes references herein as a "***fabrication station***". FIG. 4 also illustrates an apparatus for receiving an addressable array, in particular a single "user station", which is remote from the fabrication station. The user station includes a processor 162, a memory 184, a ***scanner*** [*i.e., for tracking*] 160 which can interrogate an array, a second bar code reader 182, data writer/reader 186 (which may be capable of reading/writing to the same type of media as writer/reader 320), and a communication module 264 which also has access to communication channel 180. Memory 184 can be any type of memory such as those used for memory 141. ***Scanner 160 can be any suitable apparatus for interrogating an array***, such as one which can read the location and intensity of fluorescence at each feature of an array following exposure to a fluorescently labeled sample. For example, such a scanner may be similar to the GENEARRAY scanner available from Hewlett-Packard, Palo Alto, Calif. Scanner 160 also includes though, ***a first bar code reader to read a first copy of each local bar code 356 appearing on substrate 10,*** while second bar code reader 182 can read both a second copy of each local bar code 356 appearing on a media such as label on a package 340, as well as the corresponding unique bar code 358."

Cattell, col. 10, lines 5-29; and

> "***Processor 140 then controls the fabricator, as described above, to generate the one or more arrays on substrate 10 which correspond to the received array layout information and unique identifier***. Substrate 10 carrying the arrays 12, is then sent to writer 150 which, under control of processor 140, writes a first copy of the local identifier 356 corresponding to each array onto substrate 10 in association with that array (by being physically close to it in the manner shown in FIG. 1). The substrate 10 is then sent to a cutter 152 where each individual array 12 and its associated local identifier 356 are separated from the remainder of the substrate 10, as indicated by reference number 10b, to provide multiple array units 15. For each array unit 15, printer 350, under control of processor 140, prints as bar codes on a same label 354 a second copy of the corresponding local identifier 356 as well as the corresponding unique identifier 358. Printer 350 may also print a shipping address on that or another label (which may have been received from the remote user station or elsewhere). The array unit 15 is placed in package 340 onto which label 350 is applied so that the second copy of the corresponding local identifier 356 and unique identifier are visible from the outside of package 340. Alternatively, label 350 can be placed inside package 340 along with the corresponding array

> unit 15. In either manner, the second copy of the local identifier 356 and corresponding unique identifier 358, are physically associated with the corresponding array. The resulting package is then shipped to a remote user station (which may be the same or different from the remote user station from which the array layout information and unique identifier were received)."

Cattell, col. 11, lines 20-50.

As required by the claims, Cattell also teaches preparing bioarrays by steps of deprotection (col. 1, line 28 through col. 2, line 49). Cattell also teaches a number of photolithographic approaches (col. 9, lines 50-59). As required by the last part of claim 28, the array of Cattell is planar (*i.e.*, flat; see col. 7, lines 35-65).

Although Cattell references photolithographic approaches for preparing biopolymer arrays, Cattell does not explicitly state that claimed removal of the protecting groups.

Pirrung teaches a technique for the synthesis of arrays of diverse polymers such as polypeptides and nucleic acids. The technique beneficially utilizes solid-phase chemistry techniques. Preferred embodiments utilize photolabile protecting groups, and photolithography. The technique forms polymers with monomer sequences and locations determined by the order of addition of monomers and the activation patterns formed on the substrate (see Figure 14A and description thereof). As in claim 30, Pirrung uses a different light source for irradiation.

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because each of Cattell and Pirrung are directed towards the fabrication of microarrays. One of ordinary skill in the art would have been motivated to utilize the photolithographic approach of Pirrung with the encoding and fabrication method of Cattell in view of his explicit reference to Pirrung. Therefore the invention as a whole was prima facie obvious at the time it was invented.

Claims 28-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cattell, U.S. Patent No. 6,180,351, issued on January 30, 2001, in view of Pirrung et al., U.S. Patent No. 5,405,783, issued on April 11, 1995, and Tong, U.S. Patent No. 7,163,788, issued on January 16, 2007.

Claims 28 is directed to a method of removing a protective group of a nucleotide which comprises: forming storing regions and addresses identifying the storing regions on a track which can be tracked by an optical beam on a substrate;

arranging in two or more of each of said storing regions a nucleotide having a protective group;

selecting a storing region in which a nucleotide having protective group is arranged by reading the address identifying said storing region by said optical beam;

irradiating the nucleotide having a protective group and arranged in the selected storing region by said optical beam; and

removing the protective group o£ the nucleotide having the protective group,

wherein each of said storing regions has: 1) a form o£ a concave region or a convex region of a first pregroove on said substrate; **or** 2) a flat region on said substrate. Note the "track" is interpreted to be a row or column on the array, or a line or route along which something travels or moves, such as an optical scanner. Claim 29 requires that the address positions of the array elements are prepitted.

Cattell is directed towards a method of generating an addressable array of biopolymers, such as DNA probes, on a substrate. The method includes receiving from a remote station, information on a layout of the array and an associated first identifier. A local identifier is generated corresponding to the first identifier and associated array, the local identifier being shorter in length than the corresponding first identifier. The addressable array is fabricated on the substrate in accordance with the received layout information. A first copy of the local identifier is applied to the substrate or a housing carrying the substrate. Cattell specifically teaches:

> "The above described components in FIG. 4 represent an apparatus for producing ***an addressable array***, which is sometimes references herein as a "***fabrication station***". FIG. 4 also illustrates an apparatus for receiving an addressable array, in particular a single "user station", which is remote from the fabrication station. The user station includes a processor 162, a memory 184, a ***scanner*** [*i.e., for tracking*] 160 which can interrogate an array, a second bar code reader 182, data writer/reader 186 (which may be capable of reading/writing to the same type of media as writer/reader 320), and a communication module 264 which also has access to communication channel 180. Memory 184 can be any type of memory

> such as those used for memory 141. ***Scanner 160 can be any suitable apparatus for interrogating an array***, such as one which can read the location and intensity of fluorescence at each feature of an array following exposure to a fluorescently labeled sample. For example, such a scanner may be similar to the GENEARRAY scanner available from Hewlett-Packard, Palo Alto, Calif. Scanner 160 also includes though, ***a first bar code reader to read a first copy of each local bar code 356 appearing on substrate 10,*** while second bar code reader 182 can read both a second copy of each local bar code 356 appearing on a media such as label on a package 340, as well as the corresponding unique bar code 358."

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> "***Processor 140 then controls the fabricator, as described above, to generate the one or more arrays on substrate 10 which correspond to the received array layout information and unique identifier***. Substrate 10 carrying the arrays 12, is then sent to writer 150 which, under control of processor 140, writes a first copy of the local identifier 356 corresponding to each array onto substrate 10 in association with that array (by being physically close to it in the manner shown in FIG. 1). The substrate 10 is then sent to a cutter 152 where each individual array 12 and its associated local identifier 356 are separated from the remainder of the substrate 10, as indicated by reference number 10b, to provide multiple array units 15. For each array unit 15, printer 350, under control of processor 140, prints as bar codes on a same label 354 a second copy of the corresponding local identifier 356 as well as the corresponding unique identifier 358. Printer 350 may also print a shipping address on that or another label (which may have been received from the remote user station or elsewhere). The array unit 15 is placed in package 340 onto which label 350 is applied so that the second copy of the corresponding local identifier 356 and unique identifier are visible from the outside of package 340. Alternatively, label 350 can be placed inside package 340 along with the corresponding array unit 15. In either manner, the second copy of the local identifier 356 and corresponding unique identifier 358, are physically associated with the corresponding array. The resulting package is then shipped to a remote user station (which may be the same or different from the remote user station from which the array layout information and unique identifier were received)."

Cattell, col. 11, lines 20-50.

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photolithographic approaches (col. 9, lines 50-59). As required by the last part of claim 28, the array of Cattell is planar (*i.e.*, flat; see col. 7, lines 35-65).

Although Cattell references photolithographic approaches for preparing biopolymer arrays, Cattell does not explicitly state that claimed removal of the protecting groups.

Pirrung teaches a technique for the synthesis of arrays of diverse polymers such as polypeptides and nucleic acids. The technique beneficially utilizes solid-phase chemistry techniques. Preferred embodiments utilize photolabile protecting groups, and photolithography. The technique forms polymers with monomer sequences and locations determined by the order of addition of monomers and the activation patterns formed on the substrate (see Figure 14A and description thereof). As in claim 30, Pirrung uses a different light source for irradiation.

Tong is directed towards a method of detecting or quantifying a molecular target in a sample utilizing the molecular interaction between molecular targets, bead-bound probes, and support-bound probes. Laser light or a magnetic sensor may be used to detect the beads after the interaction. The detection of the beads indicates the presence of the molecular target in the sample. Tong states:

> "FIG. 8 illustrates the particularly preferred embodiment of microarray, resembling in many ways the optical disk. The microarray is made of plastic and coated with reflective material, is circular or of any shape that spins around a central hub. ***"Pits"*** and "land" are burned or printed onto them by conventional compact disk burner technique ***to provide feedback information for the microprocessor (digital landmarks), biochip addresses and biochip contents (digital barcodes)***. At pre-programmed locations (biochip addresses), no `land` is printed. Instead, one of a pair of probes (nucleic acid, antibody, protein, or other macromolecules) is deposited and attached (printed) onto the biochip by a specially adapted arrayer of the inkjet type that is guided by a laser beam. The other of the pair is attached to beads in a separate process. The track on which the digital landmarks and biochips are located is spiral and begins from the center of the microarray as in a regular optical disk."

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because each of Cattell, Pirrung and Tong, are directed towards the fabrication of microarrays. One of ordinary skill in the art would have been motivated to utilize the photolithographic approach of Pirrung with the encoding and fabrication method of Cattell in view of his explicit reference to Pirrung. Additionally, one of ordinary skill

in the art would have been motivated to utilize the encoded scheme of Tong for the advantages of the high throughput reading and storage capabilities of the biochip. Therefore the invention as a whole was prima facie obvious at the time it was invented.

Common Ownership of Claimed Invention Presumed

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. §§ 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Conclusions

No claim is allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey S. Lundgren/
Patent Examiner, Art Unit 1639